EUROPEAN COMMISSION

Brussels, 24.8.2011
C(2011)6127 final

COMMISSION IMPLEMENTING DECISION

of 24.8.2011

amending the marketing authorisation granted by Decision C(2000)1407 for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE FRENCH AND DUTCH TEXTS ARE AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 20(7)(a) thereof,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the application submitted on 20 March 2011 by Schering Plough Europe under Article 20(3) of Regulation (EC) No 1234/2008,

Having regard to the opinion of the European Medicines Agency, formulated on 21 July 2011 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on the major variation type II and of the need to amend the marketing authorisation for the medicinal product

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 334, 12.12.2008, p. 7.
3 OJ L 311, 28.11.2001, p. 67.

"PegIntron - Peginterferon alfa-2b" which is entered in the Community Register of Medicinal Products under numbers EU/1/00/131/001-050.

(2) Schering Plough Europe has submitted, under Article 61(3) of Directive 2001/83/EC, a notification for changes to an aspect of the labelling or the package leaflet, which is not yet included in Decision C(2000)1407 of 25 May 2000.

(3) The marketing authorisation should be updated and Decision C(2000)1407 of 25 May 2000 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(4) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2000)1407 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

1) The following notification for a change to an aspect of the labelling or the package leaflet is added to the marketing authorisation:

Application number	Annex (EU numbers affected)
EMEA/H/C/280/N/096	IIIB (EU/1/00/131/001-050)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België.

Done at Brussels, on 24.8.2011.

For the Commission
Paola TESTORI COGGI
Director-General